

PATENT

Application No. 10/563,566
Docket Nos. 069044-5001-US***In the Claims:***

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-22. (Cancelled)

23. (Currently Amended) A dispenser comprising a reservoir containing a formulation for a controlled drug or drug of abuse presented in a format such that:

- (a) a patient's access to the formulation is controlled; and
- (b) the patient's access to the formulation is monitored in real time;

such that the control over the patient's usage of the formulation does not require the supervision of a healthcare professional at the time of administration.

24. (Currently amended) The [[formulation]] dispenser as claimed in claim 23, wherein the controlled drug or drug of abuse is a class A drug in a non-intravenous formulation, as defined by The Misuse of Drugs Act 1971.

25. (Currently amended) The [[formulation]] dispenser as claimed in claim 23, wherein the controlled drug or drug of abuse is an opioid.

26. (Currently amended) The [[formulation]] dispenser as claimed in claim 25, wherein the opioid is methadone or a pharmaceutically acceptable salt or derivation thereof.

27. (Currently amended) The [[formulation]] dispenser as claimed in claim 26, wherein the opioid is methadone hydrochloride.

28. (Currently amended) The [[formulation]] dispenser as claimed in claim 26, wherein the opioid is for oral delivery.

PATENT

Application No. 10/563,566
Docket Nos. 069044-5001-US

29. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 25, wherein the opioid is diamorphine or a pharmaceutically acceptable salt or derivative thereof.

30. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 29, wherein the opioid is diamorphine hydrochloride.

31. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 29, wherein the diamorphine is dry and suitable for nasal delivery upon mixing with an aqueous solution.

32. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 31, wherein the formulation for nasal delivery further comprises a solubility enhancer.

33. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 32, wherein the solubility enhancer is one or more of caffeine, sodium benzoate and sodium salicylate.

34. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 32, wherein the solubility enhancer comprises caffeine, sodium benzoate, sodium salicylate, or a combination thereof.

35. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 31, wherein the formulation for nasal delivery is a freeze-dried formulation.

36. (Currently amended) The ~~[[formulation]]~~ dispenser as claimed in claim 23, wherein a number of doses of the formulation are stored within the reservoir to be supplied to the patient.

PATENT

Application No. 10/563,566
Docket Nos. 069044-5001-US

37. (New) A dispenser comprising a reservoir containing a plurality of dosage units each of which comprise a formulation of a controlled drug or drug of abuse, said dosage units being contained in a tamper-evident manner such that:

(a) a patient's access to the dosage units is controlled; and

(b) the patient's access to the dosage units is monitored in real time;

such that the control over the patient's usage of the formulation does not require the supervision of a healthcare professional at the time of administration.

38. (New) The dispenser of claim 37, wherein more than 1 day's supply of dosage units are contained in the dispenser.